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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,370	07/06/2000	Robert C. Fahey	UCSD1130-1	6677

7590

05/06/2003

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 05/06/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/530,370

Applicant(s)

FAHEY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21February2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,40,42 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11,40,42,48-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1645

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 21 February 2003, paper #12, is acknowledged. Claims 4, 12-39, 43, 44, 45, 46, and 47 have been canceled without prejudice. Claims 1, 7, 10, 11, and 48 have been amended.

Claim 9 has not been amended because there are two forms of amendment of the claim in Applicants' Response.

Page 3 of applicants' Response lists the claim as the following:

(Twice amended) An isolated antibody which binds specifically to mycothiol or of a thiol-containing mycothiol component.

However, page 2 of Exhibit A, which is the Version with Markings to Show Changes Made lists the claim as following:

(Twice amended) An isolated antibody which binds specifically to a maleimidyl derivative of mycothiol or of a thiol-containing mycothiol component.

Clarification of which form of amended form of claim 9 is to be entered is required.

2. Claims 1-3, 5-11, 40, 42, and 48-50 are pending and under consideration.

### **Rejections Moot/Withdrawn**

3. The rejection of claims 4, 46, and 47 under 35 U.S.C. 112, first paragraph, scope of enablement for a method of detecting a member of the taxa actinomycetes comprising detecting reaction of a thiol-selective reagent with a thiol, is moot in light of the cancellation of the claims.

### **Rejections Maintained**

Art Unit: 1645

4. The rejection of claims 9-11 under 35 U.S.C. 101 non-statutory subject matter, is maintained until such time as the amendment of claim 9 (see above) is clarified.

5. The rejection of claims 1-3, 5-8, and 48-50 under 35 U.S.C. 112, first paragraph, scope of enablement for a method of detecting a member of the taxa actinomycetes comprising detecting reaction of a thiol-selective reagent with a thiol, is maintained.

Applicants argue that the amendment of claim 1 obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. While the amendment of the claim appears to obviate the originally stated rejections grounds, i.e., that Step b of claim 1 recites that one can detect actinomycetes by detecting the reaction of said reagent ~~or~~ said antibody, the newly amended form of the claim raises another scope of enablement for the rejected claims. The new form recites that the antibody specifically binds to a mycothiol derivative or a thiol-containing mycothiol component derivative. However, the specification does not support the scope of such specificity. The specification teaches only one polyclonal antibody which binds to binds to mycothiol and not its carrier proteins, and also does not bind to very specific derivatives. However, the scope of the instant claims is now drawn to any antibody which specifically binds to any/all derivatives of mycothiol..

6. The rejection of claims 5, 10, 40, and 42 under 35 U.S.C. 112, first paragraph, written description, is maintained.

Applicants argue that the specification contains detailed description of the well-known procedures by which monoclonal antibodies are prepared once an animal that produces specific

Art Unit: 1645

antibodies has been obtained. Since the specification teaches preparation of the antigen and of specific polyclonal antibodies using the antigen, those of skill in the art would not require an inventor to describe production of a monoclonal antibody to "reasonably convey" that the inventor is in possession of the claimed invention of such monoclonal antibodies.

The examiner has considered applicants' argument, but does not find it persuasive because while the specification does teach a polyclonal antibody which has certain specific binding characteristics, the specification does not actually teach that at the time of filing, the inventors had in possession any monoclonal antibodies with the claimed specificity.

#### **Conclusion**

7. Claims 1-3, 5-11, 40, 42, and 48-50 are finally rejected.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

Art Unit 1645



May 5, 2003

RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER